

From: [Henry, Tala](#)
To: [Segal, Mark](#); [McClung, Gwendolyn](#)
Cc: [Barone, Stan](#)
Subject: FW: Statement of Work
Date: Thursday, April 02, 2015 7:45:28 PM
Attachments: [REDACTED] (b) (5)
[ATT00001.htm](#)

Mark/Gwen,

See Jeff's request below.

This would be a 'task order' to the NAS. Please provide ideas/edits that would make this useful to us.

Tala R. Henry, Ph.D.
Director, Risk Assessment Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

T: 202-564-2959
E: henry.tala@epa.gov

From: Morris, Jeff
Sent: Wednesday, April 01, 2015 1:50 PM
To: Henry, Tala
Subject: FW: Statement of Work

Tala,

I would appreciate RAD's opinion on whether the statement of task in the attached proposal could be strengthened to provide for a useful NAS report. Thanks.

Jeff

From: Jones, Jim
Sent: Wednesday, April 01, 2015 12:09 PM
To: Housenger, Jack; Monell, Marty; Jordan, William; Cleland-Hamnett, Wendy; Morris, Jeff; Cunningham-HQ, Barbara; Dix, David
Subject: Fwd: Statement of Work

Let's discuss. I am inclined to support but want to get your views. Jim

Sent from my iPhone

Begin forwarded message:

From: "Stebbins, Michael J." <Michael_J._Stebbins@ostp.eop.gov>
Date: April 1, 2015 at 11:15:05 AM EDT
To: "Jones, Jim" <Jones.Jim@epa.gov>

Subject: Statement of Work

Dear Jim,

referred to
OSTP

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Mike

Michael Stebbins, Ph.D.
Assistant Director for Biotechnology
The White House
Office of Science and Technology Policy
202-456-6108

DRAFT, DELIBERATIVE, DO NOT DISTRIBUTE

**Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology
Regulatory System**

Draft: Background and Statement of Task

(b) (5)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(b) (5) [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]

[REDACTED]

From: Segal, Mark
To: Henry, Tala; Mcclung, Gwendolyn
Cc: Barone, Stan; Camacho, Iris
Subject: RE: Statement of Work
Date: Monday, April 06, 2015 8:07:37 AM
Attachments: [REDACTED]

(b) (5)

I have an edit and some comments.

(b) (5)

[REDACTED]

[REDACTED]

Mark Segal, Ph.D.
segal.mark@epa.gov
202-564-7644

From: Henry, Tala
Sent: Thursday, April 02, 2015 7:45 PM
To: Segal, Mark; Mcclung, Gwendolyn
Cc: Barone, Stan
Subject: FW: Statement of Work

Mark/Gwen,
See Jeff's request below.
This would be a 'task order' to the NAS. Please provide ideas/edits that would make this useful to us.

Tala R. Henry, Ph.D.

Director, Risk Assessment Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

T: 202-564-2959
E: henry.tala@epa.gov

From: Morris, Jeff
Sent: Wednesday, April 01, 2015 1:50 PM
To: Henry, Tala
Subject: FW: Statement of Work

Tala,

I would appreciate RAD's opinion on whether the statement of task in the attached proposal could be strengthened to provide for a useful NAS report. Thanks.

Jeff

From: Jones, Jim
Sent: Wednesday, April 01, 2015 12:09 PM
To: Housenger, Jack; Monell, Marty; Jordan, William; Cleland-Hamnett, Wendy; Morris, Jeff; Cunningham-HQ, Barbara; Dix, David
Subject: Fwd: Statement of Work

Let's discuss. I am inclined to support but want to get your views. Jim

Sent from my iPhone

Begin forwarded message:

From: "Stebbins, Michael J." <Michael_J._Stebbins@ostp.eop.gov>
Date: April 1, 2015 at 11:15:05 AM EDT
To: "Jones, Jim" <Jones.Jim@epa.gov>
Subject: Statement of Work

Dear Jim,

[REDACTED]

Mike

referred to
OSTP

Michael Stebbins, Ph.D.
Assistant Director for Biotechnology
The White House
Office of Science and Technology Policy
202-456-6108

From: [McClung, Gwendolyn](#)
To: [Henry, Tala](#); [Segal, Mark](#)
Cc: [Barone, Stan](#); [Fehrenbacher, Cathy](#)
Bcc: [McClung, Gwendolyn](#)
Subject: RE: Statement of Work
Date: Monday, April 06, 2015 10:41:51 AM

(b) (5) Tala - Here's my thoughts on the NAS Statement of Work that you may pass onto Jeff. My comments follow each of the three bullets [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Gwen

Gwendolyn McClung, Ph.D.
Assessment Branch 3
Risk Assessment Division (7403M)
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

phone: 202-564-8911
fax: 202-564-9063
email: mcclung.gwendolyn@epa.gov

From: Henry, Tala

Sent: Thursday, April 2, 2015 7:45 PM
To: Segal, Mark; Mcclung, Gwendolyn
Cc: Barone, Stan
Subject: FW: Statement of Work

Mark/Gwen,
See Jeff's request below.
This would be a 'task order' to the NAS. Please provide ideas/edits that would make this useful to us.

Tala R. Henry, Ph.D.
Director, Risk Assessment Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

T: 202-564-2959
E: henry.tala@epa.gov

From: Morris, Jeff
Sent: Wednesday, April 01, 2015 1:50 PM
To: Henry, Tala
Subject: FW: Statement of Work

Tala,

I would appreciate RAD's opinion on whether the statement of task in the attached proposal could be strengthened to provide for a useful NAS report. Thanks.

Jeff

From: Jones, Jim
Sent: Wednesday, April 01, 2015 12:09 PM
To: Housenger, Jack; Monell, Marty; Jordan, William; Cleland-Hamnett, Wendy; Morris, Jeff; Cunningham-HQ, Barbara; Dix, David
Subject: Fwd: Statement of Work

Let's discuss. I am inclined to support but want to get your views. Jim

Sent from my iPhone

Begin forwarded message:
From: "Stebbins, Michael J." <Michael_J_Stebbins@ostp.eop.gov<<mailto:Stebbins@ostp.eop.gov>>>
Date: April 1, 2015 at 11:15:05 AM EDT
To: "Jones, Jim" <Jones.Jim@epa.gov<<mailto:Jones.Jim@epa.gov>>>
Subject: Statement of Work
Dear Jim,

referred to
OSTP

[REDACTED]

Mike

Michael Stebbins, Ph.D.
Assistant Director for Biotechnology
The White House
Office of Science and Technology Policy

202-456-6108

From: Barone, Stan
To: Morris, Jeff
Cc: Henry, Tala; Segal, Mark; McClung, Gwendolyn; Wright, Denise; Camacho, Iris; Fehrenbacher, Cathy
Subject: FW: Statement of Work
Date: Tuesday, April 07, 2015 3:46:12 PM
Attachments: [REDACTED]

(b) (5)

Jeff,

As a follow-up to your request on comments on the NAS SOW, I am forwarding comments from Mark and Gwen that we would like to discuss at Thursday biotech meeting. [REDACTED]

(b) (5)

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

Stanley Barone Jr., M.S., Ph.D.
Deputy Director Risk Assessment Division
Office of Pollution Prevention and Toxics
US Environmental Protection Agency

202.564.1169 office
202.564.7450 fax
202.253.5079 bb

Tala - Here's my thoughts on the NAS Statement of Work that you may pass onto Jeff. [REDACTED]

(b) (5)

[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Gwen

From: Segal, Mark
Sent: Monday, April 06, 2015 8:08 AM
To: Henry, Tala; Mcclung, Gwendolyn
Cc: Barone, Stan; Camacho, Iris
Subject: RE: Statement of Work

I have an edit and some comments.

(b) (5)

[REDACTED]

[REDACTED]

[REDACTED]

Mark Segal, Ph.D.
segal.mark@epa.gov
202-564-7644

From: Henry, Tala
Sent: Thursday, April 02, 2015 7:45 PM
To: Segal, Mark; Mcclung, Gwendolyn
Cc: Barone, Stan
Subject: FW: Statement of Work

Mark/Gwen,
See Jeff's request below.
This would be a 'task order' to the NAS. Please provide ideas/edits that would make this useful to us.

Tala R. Henry, Ph.D.
Director, Risk Assessment Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

T: 202-564-2959
E: henry.tala@epa.gov

From: Morris, Jeff
Sent: Wednesday, April 01, 2015 1:50 PM

To: Henry, Tala
Subject: FW: Statement of Work

Tala,

I would appreciate RAD's opinion on whether the statement of task in the attached proposal could be strengthened to provide for a useful NAS report. Thanks.

Jeff

From: Jones, Jim
Sent: Wednesday, April 01, 2015 12:09 PM
To: Housenger, Jack; Monell, Marty; Jordan, William; Cleland-Hamnett, Wendy; Morris, Jeff; Cunningham-HQ, Barbara; Dix, David
Subject: Fwd: Statement of Work

Let's discuss. I am inclined to support but want to get your views. Jim

Sent from my iPhone

Begin forwarded message:

From: "Stebbins, Michael J." <Michael_J._Stebbins@ostp.eop.gov>
Date: April 1, 2015 at 11:15:05 AM EDT
To: "Jones, Jim" <jones.jim@epa.gov>
Subject: Statement of Work

referred to
OSTP

Dear Jim,

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Mike

Michael Stebbins, Ph.D.
Assistant Director for Biotechnology
The White House
Office of Science and Technology Policy
202-456-6108

From: Morris, Jeff
To: Segal, Mark; Mcclung, Gwendolyn
Cc: Henry, Tala
Subject: FW: Draft NAS Task Statement
Date: Monday, April 27, 2015 4:10:26 PM
Attachments: [REDACTED]

(b) (5)

Mark and Gwen,

The attached contains combined OPP-OPPT comments on the proposed NAS task statement. I think it incorporates your input. (I had to print the doc to see the redline/strike-outs, which don't show up on my computer screen.)

Jeff

From: Morris, Jeff
Sent: Monday, April 27, 2015 7:32 AM
To: 'Nalubola, Ritu'; Jordan, William; Firko, Michael J - APHIS; McKalip, Doug - OSEC
Subject: Draft NAS Task Statement

Ritu,

Thanks for sharing FDA's comments.

All,

Attached are EPA's comments on the task statement for the proposed study, "Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System." I understood from Robbie that he's hoping to get a consolidated set of comments from us. If FDA and USDA are ok with that, then please feel free to add to the attached and send back to me. If you would like a call to discuss comments, I'm happy to have one set up. Thanks.

Jeff

Jeffery T. Morris, PhD
Deputy Director, Office of Pollution Prevention & Toxics
US Environmental Protection Agency

1200 Pennsylvania Avenue, NW (MC-7401M)
Washington, DC 20460

(202) 564-6756

From: Nalubola, Ritu [<mailto:Ritu.Nalubola@fda.hhs.gov>]

Sent: Friday, April 24, 2015 2:43 PM

To: Jordan, William; Morris, Jeff; Firko, Michael J - APHIS; McKalip, Doug - OSEC

Cc: Linden, Carol; Cournoyer, Patrick

Subject: RE: Review draft memorandum

referred to
FDA

[REDACTED]

Ritu Nalubola, Ph.D.

Senior Policy Advisor

Office of Policy, Office of the Commissioner

U.S. Food and Drug Administration

WO32, Room 4236

Phone: 301-796-3252

Fax: 301-847-3541

Email: Ritu.Nalubola@fda.hhs.gov

From: Jordan, William [<mailto:Jordan.William@epa.gov>]

Sent: Monday, April 20, 2015 12:19 PM

To: Firko, Michael J - APHIS; Barbero, Robbie; Nalubola, Ritu; Costanza, Jed; Bucknall, Janet L - APHIS; Morris, Jeff

Cc: Stebbins, Michael J.; McKalip, Doug - OSEC

Subject: RE: Review draft memorandum

Robbie –

Both EPA's pesticide group and toxic substances group are interested in the NAS project. Jeff Morris, the Deputy Director for the Office of Pollution Prevention and Toxics can present his group's views, and he will be contacting you directly about what time works for him.

Unfortunately, I have Advisory Committee meeting at both of the times you propose. Would it be possible for me to come late in the afternoon on Friday, i.e., after 5 PM? If not, I will ask Jeff Morris to convey my ideas.

Thanks,

Bill

William Jordan

Deputy Director, Programs

Office of Pesticide Programs

U. S. Environmental Protection Agency

Phone: 703-305-1049

Fax: 703-308-4776

Mailing Address:

USEPA Headquarters

Clinton Building

1200 Pennsylvania Ave., NW

Mail Code (7501P)

Washington, DC 20460

Courier Address:

Potomac Yards South

2777 Crystal Drive

Room 12-235

Arlington, VA

From: Firko, Michael J - APHIS [<mailto:Michael.J.Firko@aphis.usda.gov>]

Sent: Monday, April 20, 2015 11:58 AM

To: Barbero, Robbie; 'Ritu.Nalubola@fda.hhs.gov'; 'Jed.Costanza@fda.hhs.gov'; Bucknall, Janet L - APHIS; Jordan, William; Morris, Jeff

Cc: Stebbins, Michael J.; McKalip, Doug - OSEC

Subject: RE: Review draft memorandum

Robbie,

referred to
USDA

[REDACTED]

[REDACTED]

Mike

Michael J. Firko, Ph.D., Deputy Administrator
Animal and Plant Health Inspection Service (APHIS)
Biotechnology Regulatory Services (BRS)
United States Department of Agriculture (USDA)
4700 River Road, Unit 98
Riverdale, MD 20737
Riverdale: (301) 851-3941
DC: (202) 799-7103
mobile: (202) 230-8686

From: [Segal, Mark](#)
To: [Morris, Jeff](#)
Cc: [Mcclung, Gwendolyn](#); [Penalva-Arana, Carolina](#)
Subject: Fw: Request for Information from NAS Committee on Future Biotech Products
Date: Friday, June 24, 2016 9:03:03 AM
Attachments: [image001.png](#)
[RFI-NAS-Committee-EPA-OPPT.docx](#)

Jeff,

Am forwarding to Gwen and Carolina to make sure we have complete coverage.

From: Laney, Kara N. <KLaney@nas.edu>
Sent: Thursday, June 23, 2016 4:37 PM
To: Morris, Jeff
Cc: Segal, Mark; Edelstein, Rebecca
Subject: Request for Information from NAS Committee on Future Biotech Products

Dear Dr. Morris,

I am study director with the National Academies of Sciences, Engineering, and Medicine. I am currently directing the study on future biotechnology products and opportunities to enhance capabilities of the biotechnology regulatory system. The committee is wrapping up the information-gathering phase of the study, and as a part of that, it has put together an RFP to learn about the research investment being made by the federal government in biotechnology.

As you know, in response to a request from the White House Office of Science and Technology Policy, the Academies have convened a committee of experts to identify the kinds of products that may be produced with biotechnology in the next 10 years. The U.S. regulatory system for biotechnology products was originally designed in the 1980s, so the committee will also provide advice on the scientific capabilities, tools, and expertise that may be necessary to regulate those forthcoming products and on whether potential future products could pose different types of risks relative to existing products and organisms. The committee's report is expected to be released at the end of 2016.

The RFP is attached, and it includes a list of suggested search terms as guidelines for the research topics the committee is interested in. The committee would appreciate information about research projects being conducted by the Office of Pollution Prevention and Toxics. A separate request is being sent to the Office of Pesticide Programs. To be of use to its report writing process, the committee set a due date of July 25.

Thanks in advance for your help with this request and please let me know if I can answer any questions.

Best regards,

Kara

Kara Laney

Study Director

Board on Agriculture and Natural Resources

The National Academies of

SCIENCES • ENGINEERING • MEDICINE

500 Fifth Street NW Washington, DC 20001

Phone: 202-334-1954 Fax: 202-334-1978